Our team recently moved from University of Alabama at Birmingham to New York, where we established, with participation of Dr. Jeffrey Moses, New York Cardiac and Vascular Institute at Lenox Hill Hospital. Since 1994, simultaneously with other centers, we set up our goal to develop alternative revascularization technique for extracranial stenotic atherosclerotic disease on brachiocephalic arteries with special attention to lesions in vicinity of the bifurcation of the carotid artery. The word “alternative” is very important, because we did not want to treat only lesions vascular surgeons turned down for variety of reasons, such as post radiation stenoses, post endarterectomy restenosis, high internal carotid artery lesions or stenoses on old, e.g. debilitated patients with multiple risk factors, but to develop real and viable alternative to endarterectomy. This approach of course stimulated passionate criticism and created significant interdisciplinary tension, at least at the UAB.

Our present material consists of 345 patients who underwent carotid angioplasty with stenting (CAS). On these patients we stented 392 carotid arteries, i.e. 47 patients (13%) underwent bilateral CAS, some of them as one intervention, occasionally in two separate procedures. Thirty-eight patients (11%) presented with contralateral internal carotid artery occlusion. Sixty-six vessels (17%) were treated because of post endarterectomy (EAC) restenosis. Eighty percent of our patients were ineligible for NASCET. The study includes both symptomatic (42%) and asymptomatic patients with 60% carotid stenosis. The only exclusions have been severely tortuous, diseased aortic arch and vessels and presence of a mobile thrombus at the lesion site.

Over the past 12 months the clinical protocol has been simplified. Neurological status at baseline, post-procedure and at follow-up is assessed by an independent neurologist using NIH Stroke Scale. Complete cerebral angiography is done on all patients prior to stenting as a separate examination or immediately before stenting. The knowledge of overall brain blood supply, conditions of other brachiocephalic arteries, status of circle of Willis and absence of other intracranial vascular pathology (stenosis, aneurysm, arterio-venous malformation) is very important to avoid certain complications of CAS. Duplex ultrasound is required pre- and post-stenting and used as a base line for follow-up at six months and thereafter. Only symptomatic patients, especially those with history of stroke undergo CT or MRI scanning. For 48 hours before the procedure, patients are treated with aspirin 325 mg and ticlopidine 250 mg bid. Same day admissions and 23-hour discharges are done when possible.

The technique of CAS was simplified as well. If the intervention follows cerebral angiography, 5 Fr diagnostic catheter (if needed) is advanced into the external carotid artery over 0.038 glide wire. This glide wire is replaced with 0.038 exchange wire (glide or Amplatz), diagnostic catheter is withdrawn and 7 Fr 90 cm sheath is advanced into the common carotid artery, just below the carotid bifurcation. If CAS is done separately from...
diagnostic cerebral angiography, the 7 Fr sheath is placed in the descending aorta approximately 6 cm below aortic arch. With a 125 cm 5 Fr catheter carotid artery is catheterized. Bifurcation is visualized and 5 Fr catheter (if needed) is advanced into the external carotid artery. Then the 7 Fr sheath is slid over the catheter wire combination into its position within the common carotid artery. The patient is given Heparin to raise the ACT to approximately 200-250 sec (HemoTec method). The stenotic lesion is crossed with a 0.014 wire and predilated with a 4 x 40 mm PTA balloon (0.018” compatible). This PTA balloon is advanced — either pre- or post-inflation — into the distal internal carotid artery and the 0.014 wire is replaced by a 0.018 exchange wire and the balloon is removed. The unconstrained diameter of the self-expanding stent to be deployed should be approximately 1–2 mm larger than the largest segment to be covered by the stent. Typically, 8 mm x 20 mm and 10 mm x 20 mm stents are used. The stent is post dilated with 5 or 6 mm x 20 mm balloon, the size of the dilatation balloon depends on the size of the internal carotid artery. Although the internal carotid artery is commonly 2–3 mm smaller than the common carotid artery, follow-up studies have shown that oversizing the stent in the internal carotid artery does not cause late problems. To cover the external carotid artery with a stent does not cause any problems either, follow-up studies showed external carotid artery to be patent with rare exceptions. If the external carotid artery becomes significantly stenosed or occluded after post-dilatation of the stent, this vessel can be approached through stent mesh and reopened. Sheath is removed when the ACS is < 150 sec and the patient is discharged the next morning. Continuous monitoring of the heart rate and blood pressure throughout the intervention is mandatory, significant variations are not uncommon. Good hydration and maintenance of a appropriate blood pressure are important in the recovery period.

Results of CAS are very promising. Technical success has been 98%. Early failures and complications were related to relative inexperience with new procedure and lack of dedicated equipment. Overall, 30-day mortality and morbidity for 345 patients/392 vessels have been as follows: death 2.5% (3 = 0.9% neurological, 5 = 1.4% systemic), 0.9% major disabling strokes (from 3, only one related to the intervention) and 6.1% minor strokes. From these 24 minor strokes, 12 were in the realm of TIAs with complete neurological recovery. As expected, there is a powerful learning curve effect. In the last 102 procedures, there has been one minor stroke and one TIA, for overall 30-day complication rate of 2%.

Control angiography and/or duplex ultrasound has been completed at six months on approximately 80% of eligible patients. Restenosis, defined as a greater than 50% diameter stenosis, was identified in 5% of these patients. From 20 restenosed carotid arteries, 13 were due to the collapse of the balloon-expandable stent. In only three patients, the restenosis was of such a degree, that they underwent successful repeat angioplasty without any complications. Two patients underwent CEA with uncomplicated removal of the stent. Repeat PTA for restenosis is simple and safe.

In this registry, 95% of patients are in clinical follow-up. There has been one neurological death (intracerebral hemorrhage), one major and three minor strokes. Based on intention to prevent neurological symptoms due to carotid arteriosclerotic stenoses, freedom from neurological death or any stroke at two years was 92 ± 1%. These numbers suggest that carotid angioplasty with stenting (CAS) is effective and durable method for preventing stroke patients with extra-cranial carotid stenoses.

Cost of the CAS intervention compares favorably with surgical endarterectomy. Replacement of balloon-expandable stents for one self-expandable stent and simplification of the access equipment significantly lowered the cost. Local anesthesia and short hospital stays are also contributing factors.

Stent thrombosis, as already mentioned, is not an issue.

Taking into consideration our results, we think that carotid angioplasty with stenting is safe, effective and durable treatment for carotid stenosis and that it prevents ischemic strokes. Certainly it is less invasive than carotid endarterectomy with comparable cost.

**PANEL DISCUSSION**

BUDDY CONNORS: What you all are doing is groundbreaking and I have basically one question to ask on this. Of all the various pieces of the pie that you put together, wires, guide catheters, balloons and stents, which of these needs the least improvement and which of these needs the most improvement?

JIRI VITEK: To start with — in carotid angioplasty and stenting the most essential thing is to put together a team with all the necessary knowledge and skills. Now to your question: stents need the most improvement and then the development of a workable filter to be placed in the distal internal carotid artery is necessary. The “French” approach to preventing emboli — temporary occlusion of the distal internal carotid artery — carries its technical and other problems. At least 10% of our patients do not tolerate even short occlusion of the ipsilateral internal carotid artery. The occlusion mini-balloon, being attached to 300 cm mini-catheter, has to be inflated and deflated several times and the segment of the internal carotid artery, proximally to the mini-balloon, has to be...
increases the cost. So then you do MRI and MRA which within the intracranial circulation. It sounds almost like nial pathology including aneurysm, AVMs and stenoses. Additionally you have no idea of more distal ultrasound predicts. So you operate on a number of 60%–80% stenosis, and the stenosis is usually less then the community practice, Duplex ultrasound indicates a priori form endarterectomy without angiography. In Doppler studies, all these investigational procedures, biliary stents, (we now use 1 stent). When we were rou-

BUDDY CONNORS: What sort of stent do you think is going to eventually be the best?

JIRI VITEK: Self expanding stents, no doubt about it. The presently available self-expanding stents in the U.S. are far from ideal. The stents should be specifically designed for carotids. They should be softer and more pliable to accommodate the tortuosities of the internal carotid artery, so once deposited, they would not straighten the vessel. The present delivery system is too rigid and should also be of smaller size. Perhaps the stents should be capable of differential expansion.

BUDDY CONNORS: What guidewire do you all use?

JIRI VITEK: To catheterize the common carotid artery we use 0.038 glide-wire. To advance 7 Fr 90 cm sheath over a 5 Fr catheter into the common carotid artery we use 0.038 glide or an Amplatz exchange wire. To cross the stenosis we use a variety of 0.014” wires, depending on the anatomy of the bifurcation, stenosis and distal internal carotid artery. We advance this wire approximately to the level of petrous portion. Then, having the tip of the pre-dilatation balloon securely in the healthy neck portion of the internal carotid artery, the 0.014” wire is exchanged for the stiffer 0.018” exchange wire, which we use to advance and deposit the stent.

FRANK CRIADO: Dr. Vitek, that was a very good presentation and an impressive series. Why don’t you comment upon one small point, about the cost? What I wanted to ask you is this: how can you possibly do carotid stenting for less money when today we do virtually every carotid endarterectomy without angiography. Only about 20% of the patients end up in ICU and most of them go home within 2 days! How can you possibly spend less with carotid stenting?

JIRI VITEK: In my judgment it is imprudent to perform endarterectomy without a priori angiography. In community practice, Duplex ultrasound indicates 60–80% stenosis, and the stenosis is usually less then the ultrasound predicts. So you operate on a number of 60% stenoses. Additionally you have no idea of more distal stenotic lesions on the internal carotid artery, intra-cranial pathology including aneurysm, AVMs and stenoses within the intracranial circulation. It sounds almost like malpractice. So then you do MRI and MRA which increases the cost.

FRANK CRIADO: Well we could certainly have a discussion on that, but not at this time. It’s a difficult topic altogether.

JIRI VITEK: First, the cath lab rooms are significantly cheaper to use then the operating rooms. Then we significantly simplified the procedure and we limited our equipment. Presently we use fewer tools to get into the common carotid artery and then, on average, we use only two balloons, one to pre-dilate and one to dilate the stent. And of course one stent. We do not use an anesthesiologist and most of our patients are admitted for 23 hours.

GARY ROUBIN: Let me make just one point about the cost for Frank. Frank, what we’re doing now routinely is bringing the patients in with full vessel study and then going straight on into stenting. So it’s all in the one procedure now, there’s no additional cost for the full vessel. So it isn’t done in the same procedure. In terms of the stay these patients come in, they go home within 23 hours through 7 French. They don’t go to an ICU, not even for one day. So that’s why it’s going to be a less expensive procedure. And I also point out that the cost of these procedures comes from the complication rates and I think there will be less complications. Let me just make many points about comparing complications in non-comparable series. You know, you can’t compare retrospective case counting from the Cleveland Clinic or anywhere else to a prospective collection as we heard from Dr. Londero. You just can’t compare these results.

The only study reported in recent years where there was prospective evaluation by neurologists shows a 5.6% stroke and death rate. And one other interesting point which I think the vascular surgeons must acknowledge. This came from a vascular surgeon to me recently about the NASA trial. The surgeons never talk about the 30 day complications in the NASA trial. The total complications including some renal failure, pneumonia, cranial nerve pulls, ICU admissions for all these things was 18%. Now I have never seen that reported. Why? So I’m not sure that we know exactly how inexpensive endarterectomy is. We need to keep these things in mind.

RICHARD STACK: Gary, before you leave the microphone, just kind of set the record straight. If I remember correctly I saw a paper by your surgical colleagues at Alabama, doing the same sort of calculations and their bottom line came out in a different way. Could you clarify that?

GARY ROUBIN: Yes. Will Jordan, the surgeon, looked at the first 100 patients when we were using 3–4 biliary stents, (we now use 1 stent). When we were routinely doing SPECT, MRI’s before and after, transcranial Doppler studies, all these investigational procedures,
keeping the patients around for days and days for a protocol, you compare the total cost of all those things, additional 4 vessel angiography with what he was doing in his routine surgical practice. It was an absolutely irrelevant type of comparison. We look at what we do today for our routine clinical cases compared to what he’s doing, we see the sort of numbers that Jiri just showed a few minutes ago.

PHILIP WALKER: Jiri, just one comment about the cerebral hyperperfusion problem. That’s something surgeons have certainly been aware of for a long time and it’s very worrying when you see it. Fortunately, it’s uncommon. Certainly anyone who gets a headache or any hypertension we jump on that very aggressively with steroids and anti-hypertension medication very quickly. With the cost in mind, the procedure evolves and much of the ancillary invasive imaging is avoided as has occurred with carotid endarterectomy. I agree entirely with Gary, that the costs are going to come down. The cost is also going to be related to the acute complication rate. Strokes are very expensive. Gary, to clarify your presentation, could you tell us the breakdown of the morbidity for asymptomatics and symptomatics. Could I also make a plea to everyone who is reporting work in this field to report results separately for the subgroups of patients according to their symptomatic status. Certainly in the surgical literature results are very different for asymptomatics as opposed to symptomatics. I think to lump them all in together is inappropriate.

JIRI VITEK: I agree with you. Unfortunately in our statistics we did not divide our complication rate between symptomatic and asymptomatic patients. In this regard my impression is, that there was no difference in complication rate between symptomatic and asymptomatic patients.

What we know for sure is, that we had more complications in asymptomatic patients older than 80 years. As far as post-endarterectomy restenoses, in 47 treated vessels we had one minor stroke. As I already mentioned in my presentation, there is a significant learning curve, in the last 100 interventions we had 2% over all complication rate.

JUAN PARODI: I have a technical question about treating restenosis. We are treating patients with restenosis with balloon and stenting and in one case, I couldn’t dilate the lesion, even with a high pressure balloon, trying to predilate. I was not sure. I had to place a stent before because I was concerned about having the stent inside and not being able to dilate it. Have you ever seen a case like that, where you could not dilate even with a high pressure balloon and tight stenosis?

JIRI VITEK: We have the problem with recoil. After pre-dilatation with 4 mm balloon the stenosis returned to its original tightness, so we had to use a bigger balloon for predilatation. Then we had problems with heavily calcified stenoses, they require really high pressure, up to 20 atm. We never had problems — as far as I remember — to dilate postendarterectomy restenosis.

JUAN PARODI: What would you do in that case? You cannot predilate the lesion with the high pressure balloon, try a stent?

JIRI VITEK: If you fully inflate a 4 mm balloon and the stenosis is as tight as before, you should use a bigger balloon for predilation up to the point when the self-expandable stent can be easily passed through. Once you open the stent, recoil is usually much smaller, especially after dilating the stent.

JUAN PARODI: Yeah, we worked better with intervention, we went on to more than 20 and we couldn’t open that.

JIRI VITEK: If after everything I suggested, the self-expanding stent does not pass through the stenosis, mount a 4 or 5 mm balloon — balloon-expandable stent — and open this stent within the stenosis. Then through this stent you can easily pass a self-expanding stent system.